

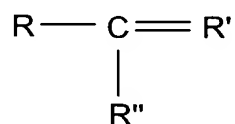
WHAT IS CLAIMED IS:

1. An assay device for detecting the presence or absence of amines within a test sample, said assay device comprising a fluidic medium that defines a detection zone, wherein a chemichromic dye is contained within said detection zone, said chemichromic dye being capable of undergoing a detectable color change upon reaction with one or more amines.

2. An assay device as defined in claim 1, wherein said chemichromic dye is an arylmethane.

3. An assay device as defined in claim 2, wherein said arylmethane is selected from the group consisting of diarylmethanes and triarylmethanes.

4. An assay device as defined in claim 2, wherein said chemichromic dye is a triarylmethane having the following general structure:



wherein R, R', and R'' are independently selected from substituted and unsubstituted aryl groups.

5. An assay device as defined in claim 4, wherein said aryl groups are phenyl groups, naphthyl groups, or anthracenyl groups.

6. An assay device as defined in claim 5, wherein at least one of said aryl groups is amino-substituted, hydroxyl-substituted, carboxyl-substituted, sulfonic-substituted, alkyl-substituted, carbonyl-substituted, or combinations thereof.

7. An assay device as defined in claim 4, wherein said triarylmethane is pararosanilin, alpha-naphtholbenzein, naphthocrome green, or analogs thereof.

8. An assay device as defined in claim 3, wherein said chemichromic dye is a diarylmethane.

9. An assay device as defined in claim 8, wherein said diarylmethane is 4,4'-bis (dimethylamino) benzhydrol or analogs thereof.

10. An assay device as defined in claim 1, wherein said fluidic medium is a porous membrane.

11. An assay device as defined in claim 1, wherein said fluidic medium includes at least one flow channel.

12. An assay device as defined in claim 1, wherein said fluidic medium is in

fluid communication with detection probes.

13. An assay device as defined in claim 12, wherein said detection probes are conjugated with a specific binding member for the analyte.

14. An assay device as defined in claim 13, wherein said fluidic medium defines a second detection zone within which is immobilized a capture reagent, said capture reagent being configured to bind to said detection probes or complexes thereof to generate a detection signal, wherein the amount of an analyte in the test sample is proportional to the intensity of said detection signal.

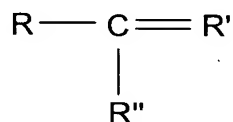
15. An assay device as defined in claim 1, wherein said fluidic medium further defines a control zone within which a chemichromic dye is contained, said control zone being located downstream from said detection zone.

16. An assay device for detecting the presence or absence of both amines and an analyte within a test sample, said assay device comprising a porous membrane that is in fluid communication with detection probes conjugated with a specific binding for the analyte, said porous membrane defining:

a first detection zone within which a triarylmethane dye is immobilized, said triarylmethane dye being capable of undergoing a detectable color change upon reaction with one or more amines; and

a second detection zone within which a capture reagent is immobilized, said capture reagent being configured to bind to said detection probes or complexes thereof to generate a detection signal, wherein the amount of an analyte in the test sample is proportional to the intensity of said detection signal.

17. An assay device as defined in claim 16, wherein said triarylmethane has the following general structure:



wherein R, R', and R'' are independently selected from substituted and unsubstituted aryl groups.

18. An assay device as defined in claim 17, wherein said aryl groups are phenyl groups, naphthyl groups, or anthracenyl groups.

19. An assay device as defined in claim 18, wherein at least one of said aryl groups is amino-substituted, hydroxyl-substituted, carboxyl-substituted, alkyl-

substituted, sulfonic-substituted, carbonyl-substituted, or combinations thereof.

20. An assay device as defined in claim 16, wherein said triarylmethane is pararosanilin, alpha-naphtholbenzein, naphthocrome green, or analogs thereof.

21. An assay device as defined in claim 16, wherein said porous
5 membrane further defines a control zone within which a chemichromic dye is contained, said control zone being located downstream from said detection zone.

22. A method for detecting the presence or absence of amines within a test sample, said method comprising:

i) contacting an assay device with a test sample containing one or more
10 amines, said assay device comprising a fluidic medium that defines a detection zone, wherein a chemichromic dye is contained within said detection zone that undergoes a color change upon reacting with said amines; and

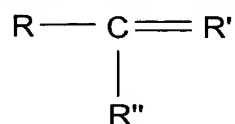
ii) measuring the color intensity of said chemichromic dye at said detection
15 zone after reacting with said amines, wherein said color intensity corresponds to a certain concentration of said amines within the test sample.

23. A method as defined in claim 22, further comprising comparing the measured color intensity with a color intensity of a chemichromic dye that is not reacted with amines.

24. A method as defined in claim 23, wherein said chemichromic dye that is
20 not reacted with amines is contained within a control zone, said control zone being defined by said fluidic medium and being located downstream from said detection zone.

25. A method as defined in claim 22, wherein said chemichromic dye is an arylmethane.

26. A method as defined in claim 25, wherein said chemichromic dye is a triarylmethane having the following general structure:



wherein R, R', and R'' are independently selected from substituted and unsubstituted phenyl groups, naphthyl groups, and anthracenyl groups.

27. A method as defined in claim 26, wherein at least one of R, R', or R'' is amino-substituted, hydroxyl-substituted, carboxyl-substituted, alkyl-substituted,

carbonyl-substituted, sulfonic-substituted, or combinations thereof.

28. A method as defined in claim 26, wherein said triarylmethane is pararosanilin, alpha-naphtholbenzein, naphthochrome green, or analogs thereof.

5 29. A method as defined in claim 22, wherein said fluidic medium is a porous membrane.

30. A method as defined in claim 22, wherein said fluidic medium is in fluid communication with detection probes conjugated with a specific binding member for the analyte.

10 31. A method as defined in claim 22, wherein said fluidic medium defines a second detection zone within which a capture reagent is immobilized, said second detection zone being configured to generate a detection signal.

32. A method as defined in claim 31, further comprising measuring the intensity of said detection signal, wherein the amount of an analyte in the test sample is proportional to the intensity of said detection signal.

15 33. A method as defined in claim 32, wherein said fluidic medium defines a calibration zone that is configured to generate a calibration signal.

34. A method as defined in claim 33, further comprising calibrating the intensity of said detection signal with the intensity of said calibration signal.

20 35. A method as defined in claim 22, wherein the presence of said amines in the test sample reflects the presence of infection.

36. A method as defined in claim 35, wherein the test sample is obtained from vaginal fluid.

37. A method as defined in claim 35, wherein the test sample is obtained from a wound exudate.

25 38. A method as defined in claim 35, wherein the test sample is obtained from food.